**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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| Applicant | : | Klautky, et al. |
| Appl. No. | : | **10/676,568** |
| Filed | : | September 30, 2003 |
| Title | : | AUTOMATED CYTOLOGICAL SAMPLE CLASSIFICATION |
| Examiner | : | Lyle Alexander |
| Group Art Unit | : | 1797 |
| Confirm. No. | : | 7905 |

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**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicants respectfully request a pre-appeal brief conference. No amendments are being filed with this request. Therefore, claims 1, 5-7, 10, 11, 14, 15, 21-24, 28, 29, and 39-41 remain pending in this application. Applicants respectfully submit that the Final Office Action dated January 19, 2010 (hereinafter "the Final Office Action") includes clear errors, which are described in further detail below.

Weid does not teach or suggest "obtaining an additional cytological sample from the patient"

In response to Applicants' argument previously presented in the first paragraph on p. 3 of the Response filed October 30, 2009 (hereinafter "Applicants' Response") that Weid has not been characterized as teaching the claimed invention, the Examiner (in the middle of p. 6 of the Final Office Action) refers specifically to the NPL documents submitted on June 9, 2009. However, the characterization that the Examiner is referring to is a characterization made by the Australian Patent Office, not a characterization made by the Applicants. Furthermore, the characterization of Weid by the Australian Patent Office does not include any finding or

suggestion that Weid teaches the step of obtaining an addition cytological sample from the patient, as required by the claims of the present application.

Independent claims 1 and 41 require the steps of obtaining an initial sample from a patient and obtaining an additional sample from the patient. The Examiner states (in the first full paragraph on p. 7 of the Final Office Action) that the step of obtaining an additional sample from the patient is construed as "obtaining additional sample from the vessel where it has been collected." This interpretation is unreasonably broad and not consistent with the specification. The specification (e.g., at p. 14, lines 3-8) and the claims clearly require that an additional sample be taken from the patient, and not from a previously obtained sample.

Further, even if the Examiner's interpretation was proper, Weid does not teach obtaining additional sample from the vessel in which it has been collected. Rather, Weid teaches a dispersing unit 14 that repeatedly pumps the sample suspension to and from the vessel 12 through tube 17 in order to cause cells or particles to disperse. Thus, the amount of sample in the system taught by Weid remains constant and Weid does not teach or suggest obtaining additional sample from the vessel where it has been collected.

Weid does not teach or suggest "attaching a manipulation designator to the vessel if the solution containing the initial sample has an adequate concentration of cellular material but requires a manipulation to render the solution containing the initial sample satisfactory for slide preparation."

Claim 1 requires that a manipulation designator is attached to the vessel if the solution containing the initial sample meets the following two conditions: 1) that the solution containing the initial sample has an adequate concentration of cellular material, and 2) that the solution containing the initial sample requires a manipulation to render the solution containing the initial sample satisfactory for slide preparation. While Weid may teach "programming that identifies an ***insufficient concentration*** and take the appropriate actions to obtain the desired concentration" (as stated by the Examiner on the top of p. 7 of the Final Office Action), that is not what is being claimed. Rather, claim 1 requires that a manipulation designator is attached to the vessel if the solution containing the initial sample has an ***adequate concentration*** of cellular material. Thus, Applicants maintain that Weid does not teach attaching a manipulation designator to the vessel if the conditions set forth in claim 1 are met.

Isenstein does not teach "attaching a positive designator to the vessel if the solution containing the initial sample has an adequate concentration of cellular material and is satisfactory for preparing a specimen slide" or "attaching a manipulation designator to the vessel if the solution containing the initial sample has an adequate concentration of cellular material but requires a manipulation to render the solution containing the initial sample satisfactory for slide preparation."

In response to Applicants' argument (previously presented in the first full paragraph on p. 6 of Applicants' Response) that Isenstein does not teach or suggest the step of attaching a positive designator as claimed or attaching a manipulation designator as claimed, the Examiner states (on the top of p. 8 of the Final Office Action) that "[t]hese remarks are not commensurate in scope with the pending claims that only require preparation of the sample within set parameters which is clearly taught by Isenstein." This statement is not well understood by the Applicants. Claim 1 recites that the positive designator indicates that the solution is satisfactory for preparing a specimen slide and that the manipulation designator indicates that the solution requires a manipulation to render the solution satisfactory for slide preparation. Thus, although a step of preparing a slide is not positively recited, a step of preparing a slide would not occur until after the designator is attached to the sample.

In contrast, Isenstein teaches a method that includes accepting or rejecting a prepared slide (e.g., in steps 124 and 126 in Fig. 6). To the extent that Isenstein's step of accepting the slide and rejecting the slide can be properly construed as "attaching a positive designator" and "attaching a manipulation designator," respectively, Isenstein does not teach or suggest that the positive designator indicates that the solution is satisfactory for preparing a specimen slide and that the manipulation designator indicates that the solution requires a manipulation to render the solution satisfactory for slide preparation.

Isenstein's acts of discarding or diluting the sample do not read on the claimed act of attaching a manipulation designator because discarding or diluting the sample as taught by Isenstein do not occur if the sample ***does have*** an adequate concentration of cellular material. In response to this argument (previously presented in the last paragraph on p. 6 of Applicants' Response), the Examiner states (in the second paragraph on p. 8 of the Final Office Action) that "the instant claim language is sufficiently broad to have been properly read on the taught

determination of cells taught by Isenstein." However, Isenstein teaches that the sample is diluted or discarded if the sample is outside of the 10-30 ASCUS+ cell range (i.e., that the sample is diluted or discarded if the sample ***does not have*** an adequate concentration of cellular material). In contrast, the claimed step of attaching a manipulation designator occurs if the sample ***does have*** an adequate concentration of cellular material. Applicants respectfully maintain that the Examiner is misinterpreting or misreading the claim language.

Isenstein does not teach or suggest "obtaining an additional cytological sample from the patient."

The Examiner did not respond to Applicants' arguments (previously presented on p. 7 of Applicant's Response) that Isenstein does not teach or suggest "obtaining an additional cytological sample from the patient." Thus, Applicants' arguments are maintained and set forth again, as follows:

In the obviousness analysis (in the first paragraph on p. 4 of the Final Office Action), the Examiner states that "[i]t is well settled to use known techniques to improve similar methods in the same way." This reasoning is not well understood because rejecting a claim based on this rationale requires "a finding that the prior art contained a "comparable" device (method, or product that is not the same as the base device) that has been improved in the same way as the claimed invention" (see MPEP §2143, Section C). The Examiner has failed to articulate such a finding.

In the obviousness analysis, the Examiner further states that it would have been within the skill of the art to modify Isenstein and add more cells to a sample with too low a concentration to gain the advantages of using the minimal amount of sample for analysis. First, Applicants submit that this obviousness rationale is not in commensurate scope with independent claims 1 and 41 because independent claims 1 and 41 require "obtaining an additional cytological sample from the patient." In contrast, the obviousness rationale supplied by the Examiner states only that it would have been obvious to add more cells to a sample, not that it would have been obvious to obtain an additional sample from a patient.

Second, because the method taught by Isenstein is performed on slides that have already been prepared, it would not have been obvious to one of ordinary skill to add cells to a slide that has already been prepared with a biological specimen. The Examiner has not provided any

teaching of adding cells to a prepared slide, and one of ordinary skill in the art would not know how to do so without contaminating the sample and/or the prepared slide.

Respectfully submitted,
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